REMARKS

I. Status of the Application

Claims 1, 3-8, 10-13 are presently pending in the application. Claims 1, 3, 4, 6-8, 10, 11 and 13 stand rejected under 35 U.S.C. §102(b) as anticipated by Boyer US Patent No. 5,100,651. Claims 1, 3-8, 10-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Superbone or Rawhide Express in view of Brilliant US Patent No. 3,591,675 and Miskewitz or Masterman and further in view of Boyer.

Applicant has amended the presently pending claims to more clearly define and distinctly characterize Applicant's claimed subject matter. Applicant respectfully requests entry and consideration of the foregoing amendment which is intended to place this case in condition for allowance.

II. Claims 1, 3, 4, 6-8, 10, 11 and 13 Are Not Anticipated by Boyer

At page 2 of the present office action claims 1, 3, 4, 6-8, 10, 11 and 13 stand rejected as being anticipated by Boyer US Patent No. 5,100,651 for reasons of record. The Examiner believes that Boyer teaches all of the elements of applicant's claimed subject matter. For example, the Examiner states that Boyer teaches bromchlorophene as a cationic antimicrobial substance. Applicant respectfully traverses the Examiner's rejection.

Applicant's invention is directed to the discovery that cationic antimicrobial substances which would otherwise be tightly bound to carriers having a negatively charged surface, such as proteinaceous carriers, can be released into saliva by alkali metal salts, so that they can be used as effective antimicrobials. No one before applicant discovered or suggested that alkali metal

salts could enhance the antimicrobial effectiveness of cationic antimicrobial substances used on carriers having a negatively charged surface.

Boyer does not teach a cationic antimicrobial substance. Bromchlorophene identified by the Examiner, is not a cationic antimicrobial substance as the structure provided at tab A by applicant demonstrates. Accordingly, applicant respectfully submits that applicant's claimed subject matter is not anticipated by Boyer.

III. Claims 1, 3-8, 10-13 are Patentable over Superbone or Rawhide Express in view of Brilliant and Miskewitz or Masterman and further in view of Boyer

At page 2 of the present office action, claims 1, 3-8, 10-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Examiner's combination of Superbone or Rawhide Express in view of Brilliant US Patent No. 3,591,675 and Miskewitz or Masterman and further in view of Boyer. Applicant respectfully traverses the Examiner's rejection of claims 1-13.

The Examiner relies on either Superbone or Rawhide Express for the teaching of a rawhide chew, i.e. applicant's claimed carrier having a charged surface. The Examiner admits that neither Superbone nor Rawhide Express teaches all of applicants claim limitations, namely a an effective antimicrobial dose of one or more cationic antimicrobial substances in a saliva soluble form positioned close to or at the surface of the carrier, and an alkali metal salt positioned close to or at the surface of the carrier and in an amount effective to promote solubility of the cationic antimicrobial substance in saliva.

Instead, the Examiner has chosen to modify Superbone or Rawhide Express to include those limitations. The Examiner relies on Brilliant for the teaching of cationic antimicrobials in mouth rinses where binding to a carrier is not an issue. No alkali metal salt, as claimed, is alleged by the Examiner to be disclosed. The Examiner also relies on Miskewitz for the teaching

of an antimicrobial in a chewing gum. No alkali metal salt, as claimed, is alleged by the Examiner to be disclosed. Masterman teaches the claimed cationic antimicrobial substance chlorhexidene gluconate with a degradable particle, however, no teaching of the presence of an alkali metal salt in an amount effective to promote solubility of a cationic antimicrobial substance in the saliva is provided, in particular when the degradable particle is proteinaceous.

Boyer fails to cure the deficiencies of the above references. Boyer does not teach a cationic antimicrobial substance. Further, Boyer does not teach an alkali metal salt in an amount effective to promote solubility of a cationic antimicrobial substance. Since Boyer does not teach a cationic antimicrobial substance, Boyer could not have contemplated the importance of an alkali metal salt to the release of a cationic antimicrobial substance from a carrier having a negatively charged surface. Accordingly, applicant respectfully submits that the Examiner's combination of references does not teach or suggest all of applicant's claim limitations.

In addition, the Examiner has not provided any indication that one of skill in the art recognized the problem associated with the binding between cationic antimicrobial substances and carriers having negatively charged substances. Applicant was the first to recognize this problem and the first to invent a solution. The Examiner's statement in the office action paper no. 5 that one would have been motivated to enhance antimicrobial efficacy is unsupported by any factual evidence. Again, no one prior to applicant recognized the release into saliva of cationic antimicrobial substances from negatively charged carriers as a problem. In addition, even if the problem was recognized, no one suggested applicant's solution of including an alkali metal salt in an amount effective to promote solubility of the cationic antimicrobial.

Applicant has demonstrated on a standard rawhide chew the unexpected and advantageous effect of the alkali metal salt in promoting the release of the cationic antimicrobial

substance into aqueous media such as saliva. See Example 2 of the specification. Example 2 demonstrates the unexpected and greatly increased release into aqueous media of the chlorhexidine digluconate antimicrobial substance when used in combination with the alkali metal salt, sodium gluconate. This advantageously allows for greater antimicrobial efficacy of the claimed device when compared with the device excluding the alkali metal salt.

Accordingly, the Examiner's combination of references does not render the claimed invention obvious.

IV. Conclusion

Having addressed all outstanding issues, Applicant respectfully requests reconsideration and allowance of claims 1, 3-8, 10-13.

Respectfully submitted,

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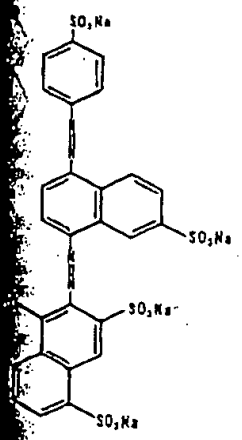
...s: Biological Products
...t Reported
...ther Names:
...apa (EU)
...apa Seed Extract
...rassica Rapa Seed
...Turnip (Brassica Rapa) Seed
...d Extract
...Mixture:
...Oing Extract (Campo)

...TIA
...e "Regulatory and Ingredient Use ... regarding use of EU Trivial names ...troduction, Part A.
...ther Name:
...Oil (U.S.)

...BLACK 1
...EINECS No.
...218-748-5
...mula:
...$_8$ • 4Na
...liant Black 1 is classed ...a disazo color. It conforms to the



...and Ingredient Use Informa... in Volume 1, Introduction,

...rces: CI 28440
...: Color Additives -

Function: Colorant
Technical/Other Names:
4-(Acetylamino)-5-Hydroxy-6-[[7-Sulfo-4-[(4-Sulfophenyl)Azo]-1-Naphthalenyl]Azo]-1,7-Naphthalenedisulfonic Acid, Tetrasodium Salt
Black PN
Brilliant Black PN
CI 28440
Food Black 1
1,7-Naphthalenedisulfonic Acid, 4-(Acetylamino)-5-Hydroxy-6-[[7-Sulfo-4-[(4-Sulfophenyl)Azo]-1-Naphthalenyl]Azo]-, Tetrasodium Salt
Trade Name:
Sicovit Brilliant Black E 151 (BASF)

BRINE SHRIMP EXTRACT

Definition: Brine Shrimp Extract is an extract of the shrimp, *Artemia salina*.
Chemical Class: Biological Products
Function: Not Reported
Technical/Other Name:
Extract of Brine Shrimp
Trade Name Mixture:
Extrait d'Artemia MPE PGS (Yves Rocher)

BROMELAIN

CAS Nos. 9001-00-7, 37189-34-7
EINECS Nos. 232-572-4, 253-384-9
Definition: Bromelain is a mixture of enzymes found in pineapple juice.
Information Sources: BAN, 21CFR184.1024, INN, JAN, MI-12(1409), TSCA, USAN
Chemical Class: Proteins
Functions: Lytic Agent; Skin-Conditioning Agent - Miscellaneous
Technical/Other Names:
Bromelain, Juice
Bromelin Ananase
Fruit Bromelain
Trade Name:
Rona/Merck KGaA - Bromelain (Rona/EM Industries)
Trade Name Mixture:
Fructinase (Serobiologiques)

BROMELIA BALANSEA

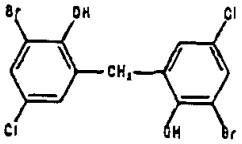
Definition: *See "Regulatory and Ingredient Use Information," regarding EU labeling names for botanical derived ingredients in Volume 1, Introduction, Part A.*
Chemical Class: Biological Products
Technical/Other Name:
Bromelia Balansea Extract (U.S.)

BROMELIA BALANSEA EXTRACT

Definition: Bromelia Balansea Extract is an extract of the bromelia, *Bromelia balansea*. *See "Regulatory and Ingredient Use Information," regarding the labeling names for botanical derived ingredients in Volume 1, Introduction, Part A.*
Chemical Class: Biological Products
Function: Not Reported
Technical/Other Names:
Bromelia Balansea (EU)
Extract of Bromelia Balansea
Trade Name Mixture:
VT-229 Extract of Bromelia (Vege-Tech)

BROMOCHLOROPHENE

CAS No. 15435-29-7
EINECS No. 239-446-8
Definition: Bromochlorophene is the halogenated aromatic compound that conforms to the formula:



Information Sources: EEC(VI/1-37)
Chemical Classes: Halogen Compounds; Phenols
Functions: Cosmetic Biocide; Deodorant Agent
Technical/Other Names:
Brophen
3,3'-Dibromo-5,5'Dichloro-2,2'-Dihydroxydiphenylmethane
3,3'-Dibromo-5,5'-Dichloro-2,2'-Dihydroxydiphenylmethane
6,6-Dibromo-4,4-Dichloro-2,2'Methylene-Diphenol
2,2'-Methylenebis[6-Bromo-4-Chlorophenol]
2,2'Methylenebis[6-Bromo-4-Chlorophenol]
Phenol, 2,2'-Methylenebis[6-Bromo-4-Chloro-

BROMOCINNAMAL

CAS No. 5443-49-2
EINECS No. 226-637-8